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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/402,446	01/18/2000	HUGH W. PRICE	7841-89	5954

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EXAMINER
HINES, JANA A

ART UNIT	PAPER NUMBER
1645	10

DATE MAILED: 12/05/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/402,446	Applicant(s) PRICE ET AL.	
	Examiner Ja-Na A Hines	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 September 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23 and 26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-23 and 26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Amendment Entry

1. The amendment filed September 7, 2001 has been entered. Claim 1 has been amended. Claim 23 has been newly added, however applicant is reminded that they incorrectly requested claim 23 to be amended when claim 23 has been newly added.. Therefore claim 23 will be treated as a newly entered claim. Claim 26 is also still incorrectly numbered and should be corrected by applicant. Claims 1-23 and 26 are under consideration in this Office Action.

Response to Amendment

2. Applicant claims that in the response to the written opinion provided by the International Preliminary Examination Authority claims 1-21 were amended to claims 1-26. However responses in the PCT application are not automatically entered into the US application. Claims 23-25 are not on file in application 09/402,446. Therefore, if applicant wishes to present additional claims into the instant application, applicant should submit new claims for this application. Applicant is reminded that prosecution of the US application is entirely separate from the prosecution of a PCT from which it only derives priority. It is suggested that applicant present any claims for which they want consideration in a timely fashion.

Withdrawal of Rejection

3. The rejection of claims 1-22 and 26 under 35 U.S.C. 112, second paragraph in view of applicant arguments.

4. The rejection of claims 9-12 under 35 U.S.C. 102(b) as being anticipated by Hirao et al., (EP 278,422) in view of applicant arguments.

Response to Arguments

5. Applicant's arguments filed September 7, 2001 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. The rejection of claims 1, 7, 9-12, 14-15, 18 and 20 under 35 U.S.C. 102(b) as being anticipated by Beggs et al. (WO 95/01155) is maintained. The rejection was on the grounds that Beggs et al., (WO 95/01155) teaches an immune globulin composition comprising an antibody and a surfactant.

Applicant urges that Begg et al., is directed to oral therapeutics and makes no mention of any use whatsoever of an antibody non-ionic surfactant combination for intravenous administration. However it is the examiner's position that the claims are not drawn to a mode of intravenous administration. The claims are drawn to a composition

wherein the compositions intended use is not patentable. Antibodies are inherently intravenous, since antibodies travel through the veins. Therefore, applicant's argument is unpersuasive.

Begg et al., teach the class of nonionic surfactant combines good compatibility with the antibodies, providing improved immunoreactivity on longer-term storage and enhancing antibody binding and/or enzyme activity. The nonionic surfactant acts as a stabilizing agent in an antibody-containing compositions, thus Beggs et al., teach the invention as claimed and the rejection is maintained.

7. The rejection of claims 1, 7, 14-15, 17-20 and 22 under 35 U.S.C. 102(b) as being anticipated by Hirao et al., (EP 278,422) is maintained for reasons previously discussed in the prior office action.

The rejection was on the grounds that Hirao et al., teach injectable solution comprising sorbitol as a stabilizer that has a low electrical conductivity which does not cause an increase of γ-globulin polymer, a rise of anticomplement titer, or impairment of the activities of the γ-globulin, either during preservation or upon administration to a living body (page 2 lines 30-36).

It is applicant's position Hirao et al., discloses sorbitol and agrues that it is not a non-ionic surfactant. However applicants teach that a non-ionic surface-active agent contains a neutral group such as a carbohydrate that can hydrogen bond with water (page 6 lines 23-25). The specification states that SPAN™, a non-ionic surface agent contains partial esters of common fatty acids and sugar alcohol anhydrides derived from

sorbitol. Sorbitol is encompassed within the specification's definition. Furthermore, sorbitol is a derivative of sorbitan, sorbitol readily undergoes dehydration to sorbitan. Therefore, Hirao et al., (EP 278,422) teach a composition of chemically unmodified complete molecular type γ-globulin that can be administered intravenously along with a non-ionic surface agent.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The rejection of claims 2-4, 8, 15-17, 19-20, 22 and 26 under 35 U.S.C. 103(a) as being unpatentable over Beggs et al. (WO 95/01155) in view of Friesen (CA 1,168,152) is maintained for reasons discussed in the previous office action.

The rejection was on the grounds that no more than routine skill would have been required at the time of applicants invention to use the known and commercially available anti-Rh_oD immune globulin as taught by Friesen with the well known serum-life enhancing stabilizers of Beggs et al., because Friesen teaches that the anti-Rh_oD immune globulin can be intravenously administered to patients to prevent Rh isoimmunization.

In response to applicant's argument that there is no suggestion to combine the references because one of skill in the art would not have been motivated to non-ionic

surfactant agents with immune globulins, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Beggs et al. (WO 95/01155) teach the class of nonionic surfactant combines good compatibility with the antibodies, providing improved immunoreactivity on longer-term storage and enhancing antibody binding and/or enzyme activity. Friesen (CA 1,168,152) teaches manufacturing of human plasma fractions contained immune globulin (IgG) wherein such fractions may be obtained in concentrated aqueous solutions and are useful for intravenous injection (page 1 lines 1-5).

One having ordinary skill in the art would have been motivated to make such a change as a mere alternative and functionally equivalent immune globulin since only the expected results of longer stability and increased immune response would have been obtained. The prior art clearly teaches that an ordinarily skilled artisan would have had a reasonable expectation of success in the exchanging of antibodies. The use of alternative and functionally equivalent antibodies would have been desirable to those of ordinary skill in the art based on the availability and improved features associated with the anti-Rh_oD immune globulin and well-known benefits of non-ionic surfactant use.

9. The rejection of claims 5-7 under 35 U.S.C. 103(a) as being unpatentable over Beggs et al. (WO 95/01155) in view of Moore et al., is maintained for reasons essentially ~~for the reasons~~ previously set forth.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. In this case, no more than routine skill would have been required at the time of applicants invention to use the known anti-c immune globulin as taught by Moore et al., with the well known serum-life enhancing stabilizers of Beggs et al., because Moore et al., teach that the anti-c immune globulin is already detectable and known to be found in human sera. One having ordinary skill in the art would have been motivated to make such a change as a mere alternative and functionally equivalent immune globulin since only the expected results of longer stability and increased immune response would have been obtained.

10. The rejection of claim 13 under 35 U.S.C. 103(a) as being unpatentable over Beggs et al. (WO 95/01155) in view of Jansen et al., (EP 318,081).

Applicant argues that Jansen does not teach the use of polysorbates to increase serum half-life of immune globulin in preparations for intravenous administration.

However, it is the examiner's position that the claims are not drawn to intravenous administration, but to a composition containing two or more non-ionic surface active agents. Jansen et al., (EP 318,081) teach the stabilization of antibodies in aqueous solutions of antibodies are physically stable for a sufficiently long time if they also contain a combination of a polyoxypropylene-polyoxyethylene block polymer (POP-POE block polymer) and a phospholipid, thus teaching the limitation of the claim.

New Grounds for Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 1-23 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is the examiner's position that the language of the claims is not as precise as the subject matter permits such that one may reasonably know the metes and bounds of the claims. The claims are indefinite because the immune globulin lacks any defining characteristics. The claims simply recite an immune globulin in a composition. There is no structural criteria such as molecular weight, deposit information, or sequence information about the immune globulin. The claim does not require that the immune globulin bind to a specific epitope or have some other define characteristic. Therefore, the identity of the immune globulin is vague and indefinite. Clarification is required in order to overcome this rejection.

12. Claims 18-19 provide for the use of an immune globulin preparation, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 18-19 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is (703) 305-0487. The examiner can normally be reached on Monday through Thursday from 6:30am to 4:00pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Ja-Na Hines

November 28, 2001

LYNETTE R. F. SMITH
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